



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,962	08/22/2003	David Farrar	PT-2683-US-NP	8400
68622	7590	02/05/2010	EXAMINER	
NORMAN F. HAINER, JR. SMITH & NEPHEW, INC. 150 MINUTEMAN ROAD ANDOVER, MA 01801			STROUD, JONATHAN R	
		ART UNIT		PAPER NUMBER
		3774		
		MAIL DATE	DELIVERY MODE	
		02/05/2010	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,962	FARRAR ET AL.	
	Examiner	Art Unit	
	JONATHAN STROUD	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04/16/2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,8-11 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,8-11 and 51-57 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/08/2009 has been entered.

Response to Arguments

Applicant's arguments filed 12/08/2009 have been fully considered but they are not persuasive.

In response to applicant's argument that the Brown reference teaches away from the use of the devices of claims 56 and 57, the office maintains that the Brown reference need teach only the structure of the device, not the reasons for using or combining. However, even assuming the prior art reference must expressly teach the reason to combine or modify the device, which the office contends it does not, the device in Brown is described for a number of uses, such as cartilage repair, tissue repair, and as a generic bio-scaffold. It would neither defeat this purpose nor render the device inoperative to modify the device of Brown in view of Evans.

In further response to that argument, applicant is also reminded that it has been held that a prior art reference must either be in the field of applicant's endeavor or, if

not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention.

See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the field of endeavor – a tissue scaffold – is in fact the same field of endeavor, making any moderate modification to the design not only reasonable but obvious to one of ordinary skill in the art.

Applicant is reminded the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 8-11, 51-53, 55 56, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 2003/0003127, further in view of Evans 2003/0236573.

Brown teaches a unitary perform device, 10, made up of a composite scaffold of a porous ceramic phase base, abstract, and a porous polymer phase, abstract.

Brown teaches that the polymer phase infiltrates the macropores of the ceramic phase, para. 0026, forming a solid interlocking perform structure.

Brown fails to teach a device that is completely non-porous when initially implanted or a device that fills the interconnected pores throughout the entire ceramic structure. Brown teaches a zone where the interconnected pores throughout the entire ceramic structure are filled, and a zone where they are not.

Evans teaches that it may be desirable to have non-porous portions of the implant, and further, specifically, an implant which is initially a porous resorbable macrostructure, where the pores of the device are filled, with a microstructure that degrades more rapidly, so that the porosity is then revealed, for the purpose of controlling the porosity of the device along a timeline that is related to the various rates of in vivo degradation.

Brown teaches a polymer/ceramic perform with differing rates of degradation.

Brown teaches that a ceramic that is free of micropores and has macropores that are filled by polymer phase, 0026, and a polymer phase that has only micropores, so that the final ceramic/polymer base is "substantially" non-porous.

Brown teaches a therapeutic additive, para. 0058.

Brown is silent as to the numerical rates of degradation, but discloses various materials.

The optimization within prior art conditions is obvious to one of ordinary skill in the art. See MPEP 2144.05. Further, the selection of a material or equivalent recognized in the prior art supports a *prima facie* case of obviousness. See MPEP 2144.06.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the two-material ceramic-polymer scaffold structure of Brown in view of Evans, to have non-porous portions of the Brown device as well, and further, that it may be desirable to have an implant which is comprised of two materials, only one of which is macroporous, which is then filled by a secondary material, so that when the secondary material is degraded, the porosity is then revealed.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on 8-4, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JONATHAN STROUD/
Examiner, Art Unit 3774

/William H. Matthews/
Primary Examiner, Art Unit 3774

Application/Control Number: 10/645,962
Art Unit: 3774

Page 7